

**CHIR0026-100 (PP023878.0001)**  
**SERIAL NO.: 10/004,113**

**PATENT**  
**FILED: October 23, 2001**

### **REMARKS**

Claims 1-19 were pending in the application.

Claims 8 and 9 were rejected.

Claims 1-7 and 10-19, withdrawn from consideration as drawn to non-elected inventions, have been cancelled without prejudice.

Claims 8 and 9 were amended to update the claims based on the election of SEQ ID NOS:53 and 54. Claims 8 and 9 were also amended to clarify that the "candidate agent" recited in part (b) of the claims is indeed the "candidate bioactive agent" recited in part (a) of the claims. Claims 8 and 9 were further amended to recite that the bioactive agent is an organic molecule. Support for this amendment can be found throughout the application as originally filed and, in particular, in paragraph [0150].

New claim 20 was added, reciting that the candidate bioactive agent is an organic compound having a molecular weight less than about 2,500 daltons. Support for new claim 20 can be found, *inter alia*, in paragraph [0150].

New claim 21 was added, reciting specific bioactivities of the CAP. Support for new claim 21 can be found, *inter alia*, in paragraph [192].

No new matter has been added.

Upon entry of this amendment, claims 8, 9 20 and 21 will be pending.

### **Rejection under 35 U. S. C. §112, first paragraph**

Claims 8 and 9 stand rejected under 35 U. S. C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that the "written description is not commensurate in scope with these method claims including ambiguous molecules broadly termed bioactive agents ..." (Office Action, page 4). Applicants traverse the rejection.

The written description requirement of §112, first paragraph, is met so long as the invention is described in the specification as broadly as it is claimed. The written description requirement ensures that, as of the filing date, the inventor conveyed with reasonable clarity to

**CHIR0026-100 (PP023878.0001)**  
**SERIAL NO.: 10/004,113**

**PATENT**  
**FILED: October 23, 2001**

those of skill in the art that he was in possession of the subject matter of the claims. *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

Applicants respectfully assert that the claimed invention complies with the written description requirement. Nonetheless, in order to further prosecution, Applicants have amended claims 8 and 9 to limit the scope of candidate bioactive agents to organic compounds. New dependent claim 20 further limits the scope of the claim to organic compounds having a molecular weight less than about 2,500 daltons.

Applicants describe methods for screening for bioactive agents throughout the application as filed, including, *inter alia*, in paragraphs [0166] through [0186] (methods of screening for a bioactive agent capable of binding to a CA protein (CAP)) and in paragraphs [0187] through [0197] (methods of screening for a bioactive agent capable of modulating the activity of a CAP).

Candidate agents are described throughout the application as originally filed and, specifically in paragraphs [0148] through [0158] and, in particular, paragraphs [0150], [0151] and [0158]. Using the specification as a guide, a person of ordinary skill in the art would know that any organic compound could be used in the claimed methods.

The art skilled would readily appreciate that Applicants were in possession of the claimed invention. Accordingly, Applicants respectfully request the rejection under 35 U. S. C. § 112, first paragraph, be withdrawn.

**Rejections under 35 U. S. C. §112, second paragraph**

Claims 8 and 9 stand rejected under 35 U. S. C. §112, first paragraph, as allegedly indefinite. The Office alleges that the terms "bioactive agent", "said candidate agent", and "bioactivity" are indefinite. Because one of ordinary skill in the art would have no difficulty understanding these terms, Applicants respectfully disagree.

The Office alleges that "it is not clear what renders an agent as [sic] bioactive" and notes that a bioactive agent "can be anything". Preliminarily, Applicants have amended the claims to recite that the bioactive agent is an organic compound. Applicants have also added new claim 21 reciting several preferred bioactivities.

**CHIR0026-100 (PP023878.0001)**  
**SERIAL NO.: 10/004,113**

**PATENT**  
**FILED: October 23, 2001**

Applicants note that the terms "bioactive" and "bioactivity" are readily understood by one of skill in the art. The application as filed states that "bioactive compounds" are:

capable of directly or indirectly altering either the carcinoma phenotype, binding to and/or modulating the bioactivity of an CA protein, or the expression of a CA sequence, including both nucleic acid sequences and protein sequences. In a particularly preferred embodiment, the candidate agent suppresses a CA phenotype, for example to a normal tissue fingerprint. Similarly, the candidate agent preferably suppresses a severe CA phenotype ..

In one aspect, a candidate agent will neutralize the effect of an CA protein. By 'neutralize' is meant that activity of a protein is either inhibited or counter acted against so as to have substantially no effect on a cell.

Paragraphs [0148] to [0149]. Additionally, in regards to the term "bioactivity", paragraph [0192] of the application as filed states that the elected protein's biological activities include "its role in tumorigenesis, including cell division, preferably in lymphatic tissue, cell proliferation, tumor growth and transformation of cells."

Applicants further point out that the Office was apparently able to determine the meaning and usage of the term "bioactive agent" when formulating the rejection under 35 U. S. C. §103.

The Office also alleges that the term "said candidate agent" in claims 8 and 9, section b, is indefinite because the term lacks proper antecedent basis. As discussed above, Applicants have amended claims 8 and 9 to clarify that the "candidate agent" recited in part (b) of the claims is indeed the "candidate bioactive agent" recited in part (a), thereby rendering the rejection moot.

The claims are clear and definite. Thus, Applicants request that the rejection under 35 U. S. C. §112, second paragraph, be withdrawn.

#### **Rejection under 35 U. S. C. §103**

Claim 8 stands rejected under 35 U. S. C. §103 as unpatentable over U.S. Patent 6,245,562 (the '562 patent) and further in view of Harlow and Lane (Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory, New York, 1988). The Office alleges that the '562 patent teaches an antibody that recognizes the MUM-2 protein (alleged to be 100% identical to

**CHIR0026-100 (PP023878.0001)**  
**SERIAL NO.: 10/004,113**

**PATENT**  
**FILED: October 23, 2001**

SEQ ID NOS:53 and 54 of the present application). The Office, although acknowledging that the '562 patent fails to teach methods of screening for antibodies, alleges that because "Harlow and Lane teach methods of screening for antibodies, bioactive agents and their binding to antigen proteins" it would have been obvious to combine the '562 patent and the Harlow and Lane reference.

Although Applicants do not agree, solely in an attempt to advance prosecution, Applicants have amended claim 8 to recite that the candidate bioactive agent is an organic compound. Applicants were unable to locate any teaching or suggestion in the '562 patent or in the Harlow and Lane reference of methods of screening for a bioactive agent capable of binding to an CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:53 and SEQ ID NO:54, said method comprising: a) combining said CAP and a candidate bioactive agent; and b) determining the binding of said candidate bioactive agent to said CAP.

Accordingly, Applicants respectfully request that the rejection under 35 U. S. C. §103 be withdrawn.

**Change of Correspondence Address**

As set forth on the attached "Change of Correspondence Address" form SB-122, Applicants respectfully request that all future correspondence related to this application be directed to:

Helen Payne  
Intellectual Property Dept.  
Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Facsimile: (510) 655-3542

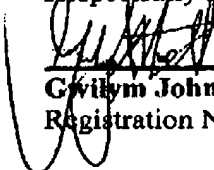
**CHIR0026-100 (PP023878.0001)**  
**SERIAL NO.: 10/004,113**

**PATENT**  
**FILED: October 23, 2001**

**Conclusion**

The examination of the pending claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6904 to clarify any unresolved issues raised by this response.

Respectfully submitted,

  
C. John Owen Attwell  
Registration No. 45,449

Date: April 28, 2005  
COZEN O'CONNOR  
1900 Market Street  
Philadelphia, PA 19103-3508  
Telephone: (215) 665-6904  
Facsimile: (215) 701-2004